DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-257/S-029

AstraZeneca LP
Attention: Ms. Cindy M. Lancaster, M.S., M.B.A.
P.O. Box 8355
Wilmington, DE 19803-8355

24 OCT 2001

Dear Ms. Lancaster:

Please refer to your supplemental new drug application dated December 13, 2000, received December 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tonocard (tocainide hydrochloride) Tablets, 400 and 600 mg.

We note that this supplement was submitted as a "Special Supplement – Changes Being Effected" under 21 CFR 314.70 (c)(2).

This supplemental new drug application provides for final printed labeling revised as follows:

The **PRECAUTIONS/Nursing Mothers** subsection has been changed from:

> It is not known whether tocainide is secreted in human milk. Because many drugs are secreted in human milk and because of the potential for serious adverse reactions in nursing infants from TONOCARD, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

to:

> Tocainide is secreted in human milk. Because of the potential for serious adverse reactions in nursing infants from TONOCARD, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

We note that the trademark and copyright statements have been added and the manufacturer/distributor addresses, AstraZeneca identity and revision date and number have been updated in the package insert. In addition, minor editorial changes were made under the **OVERDOSAGE** section.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your December 13, 2000 submission). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research